

CHAPTER 1

GENERAL INFORMATION

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1.1 PURPOSE

This directive establishes official procedures for determining Deoxynivalenol (DON) in grain and certifying the official results. This service is provided as official criteria under the authority of the United States Grain Standards Act (USGSA), as amended.

1.2 BACKGROUND

DON, also referred to as vomitoxin, is a naturally occurring mycotoxin produced by several species of Fusarium. Wet and cool weather from flowering time on to maturity promotes infection, resulting in scab or head blight in barley, wheat, oats, and rye.

The Federal Grain Inspection Service (FGIS) of the Grain Inspection, Packers and Stockyards Administration (GIPSA) provides DON testing service as official criteria for wheat, barley, oats, and corn. All official DON testing of grain is performed as prescribed in this directive by authorized employees of FGIS or licensed delegated/designated agency personnel.

Individuals wanting grains officially tested for DON should contact the nearest FGIS field office or delegated/designated agency.

DON test results are not reported to the Food and Drug Administration (FDA) because action limits are not established at this time.

1.3 DISCLAIMER CLAUSE

The mention of firm names or trade products does not imply that they are endorsed or recommended by the U.S. Department of Agriculture over other firms or similar products not mentioned.

1.4 APPROVED TEST METHODS

The methods listed below have been conformance tested to perform within FGIS specifications. Each of the approved test methods has been certified to provide results accurate up to the conformance test level at which they were approved. Any test results that are above the conformance limits are reported as exceeding the established limit unless a supplemental analysis is performed.

FGIS APPROVED TEST METHODS			
Method and Test Kit	Approved for		Conformance Limit(s)
	Qualitative	Quantitative	
Myco✓ DON (Strategic Diagnostics Inc.)		X	3 PPM
RIDASCREEN®FAST DON (r-Biopharm)		X	5 PPM
AgriScreen (Neogen)	X	X	5 PPM (quantitative test)
Veratox (Neogen)	X	X	5 PPM (quantitative test)
Fluoroquant (Romer)		X	5 PPM
AccuTox™ (Romer)		X	5 PPM
EZ-Quant DON (Diagnostix)		X	5 PPM*
EZ-Quant DON 0.5 ppm (Diagnostix)		X	2.5 PPM*
Veratox 5/5 (Neogen)		X	5 PPM**
DON FQ (Vicam)		X	5 PPM
Charm Science Rosa P/N	X		0.5 or 1.0 PPM
Diagnostix EZ-Tox		X	5 PPM

* The EZ-Quant DON Test kit (part number 600312) for barley, malted barley, wheat, and corn is approved to a conformance limit of 5 ppm. The EZ-Quant DON 0.5 ppm test kit (part number 600313) is exclusively for barley and malted barley and is approved to a conformance limit of 2.5 PPM.

** The Veratox 5/5 test kit is approved to a conformance limit of 5 ppm. Using the optional extraction procedure limits the conformance level to 2.5 ppm.

The following chart lists the DON field test kits and the grains/commodities for which they have been approved. For information concerning the testing of other grains/commodities, contact the Policies and Procedures Branch.

Test Method	Grain/Commodity							
	Barley	Malted Barley	Corn	Oats	Wheat	Wheat Flour	Wheat Midds	Rice
DON Fluoroquant	X	X	X	X	X			
DON AccuTox	X	X	X	X	X	X	X	
Veratox	X	X	X	X	X			
Veratox 5/5	X	X	X	X	X			X
AgriScreen	X	X	X	X	X			
EZ-Quant DON (0.5 -5.0)	X	X	X		X			
EZ-Quant DON (0.5-2.5)	X	X						
RIDASCREEN® FAST DON	X	X	X	X	X			X
Myco✓DON	X	X	X	X	X			
DON FQ	X	X	X	X	X			
Charm Science Rosa P/N DON	X				X			
Diachemix DON FPA					X			
Diagnostix EZ-Tox DON	X	X	X		X			

1.5 TESTING SERVICES

Applicants requesting DON testing must specify whether qualitative or quantitative testing service is desired. If qualitative analysis is requested, the applicant must specify the level desired (e.g., 1, 2 ppm). Three types of DON testing services are available as follows:

a. Submitted Sample Service.

Analysis based on a sample submitted by the applicant for service.

b. Official Sample-Lot Service.

Analysis based on an official sample obtained and analyzed by official personnel.

(1) Single lot inspection.

Samples may be obtained and tested on either an individual carrier basis or a composite sample basis (maximum of five railcars or fifteen trucks per composite sample).

(2) Unit train inspection under the CuSum Loading Plan.

Unit trains are analyzed on a subplot basis for wheat and barley and on a composite basis for other grains. Acceptable sublots must conform to contract specifications when "maximum" limits are specified.

For unit trains, the subplot size for DON testing and for grade analysis may be different. For example, an applicant may request grade analysis on the basis of a subplot containing two cars and request DON analysis on the basis of five cars.

The maximum size subplot for DON testing is five railcars for unit trains consisting of less than 200,000 bushels, or less than 50 cars. For unit trains consisting of 200,000 bushels or more, or 50 railcars or more, the maximum subplot size is ten railcars.

(3) Export shiplots

Export shiplots are analyzed on a subplot basis for wheat and barley and on a composite basis for other grains. Acceptable sublots must conform to contract specifications when "maximum" limits are specified.

The testing frequency for shiplot grain will be the same as the sample for grade analysis unless the applicant specifically requests DON analysis on the basis of a component sample.

(4) Supplemental Testing.

Upon request, supplemental testing may be performed as follows:

Composite samples may be analyzed in addition to the subplot test for wheat and barley shiplots or unit trains.

(5) Alternate Testing.

Upon request, alternate testing methods may be used, provided that the minimum testing requirements are met. Examples of alternate testing include:

- (a) Sublot testing may be used instead of composite sample analysis for grains routinely tested on a composite basis.
- (b) Grain shipments may be tested on a component sample basis in lieu of the subplot basis under the provisions of Book III, Inspection Procedures. Components are combined and averaged to determine the subplot result. Component samples will not be designated as a material portions due to DON because the FDA has not established action limits at this time. Acceptable quality will be based on the subplot result as compared to the contracted "maximum" specification.

c. Warehouse Sample-Lot Inspection Service.

Analysis based on an official sample obtained by a licensed warehouse sampler and analyzed by official personnel.

1.6 REVIEW INSPECTIONS

Sections 800.125 and 800.135 of the USGSA permit a review inspection on either official grade/factors or official criteria. When requested, a review inspection for official grade or official factor and official criteria may be handled separately even though both sets of results are reported on the same certificate.

Review inspection services for DON are provided on either a new sample or the file sample in accordance with the regulations. Board appeal inspection services are limited to the analysis of file samples.

Only one field review (reinspection or appeal inspection) is permitted for shiplot, unit train, or lash barge material portions when testing is performed on a subplot basis. However, if the applicant requests a review of the entire lot, up to three review levels of service (reinspection, appeal, board appeal) may be obtained for each subplot included in the lot. Inspection results for each review level shall replace the previous inspection result.

a. Reinspection Service.

The laboratory providing original testing services also provides reinspection services. Applicants may request either qualitative or quantitative analysis unless the original test was quantitative. Then, only a quantitative analysis is available.

b. Appeal Inspection Service.

FGIS field offices provide appeal DON testing services. Field offices not equipped to provide testing will make arrangements with another FGIS office to provide the most timely service possible. Applicants may request either qualitative or quantitative analysis unless the original or reinspection tests were quantitative. Then, only a quantitative analysis is available.

If samples are sent to a field office for analysis, write the words "**DON APPEAL**" in the "Remarks" section of the grain sample ticket and on the back of the mailing tag.

c. Board Appeal Inspection Services.

Board appeal inspection services are limited to the file sample and are provided by the Board of Appeals and Review (BAR) in Kansas City. Applicants may request either qualitative or quantitative analysis unless the original or reinspection tests were quantitative. Then, only a quantitative analysis is available. The High Performance Liquid Chromatography (HPLC) method is also available for determining DON in Board appeal samples. The applicant must specify the HPLC method as the desired determination method. Otherwise, the Board appeal inspection will be conducted using the rapid method (test kits).

When sending samples to the BAR, write the words "**DON BOARD APPEAL**" in the "Remarks" section of the grain sample ticket and on the back of mailing tag.

1.7 QUALITY ASSURANCE PROGRAM

The Technical Services Division (TSD), located at the Kansas City Technical Center, conducts a DON check sample program for all specified service points and laboratories providing testing services. TSD is responsible for preparing and distributing check samples each quarter to all official DON testing locations, analyzing check sample results, notifying field locations of any results indicating problems, and releasing a quarterly summary report to all participating laboratories. Field offices are responsible for routine supervision to assure all laboratories in their circuit provide accurate results. The TSD check sample program is designed to test the capability of the official system and to monitor the accuracy of approved testing methods. The check sample program provides limited performance information that can be used to supplement the routine supervision of official personnel performing testing services.